



## Hospital Functions

- Secondary functions:
  - Record keeping
  - Billing
  - Discharge planning, etc.

## Hospital Functions

- Services essential for hospital to run efficiently:
  - Dietary services
  - Housekeeping
  - Plant engineering

## Hospital Organization

- Three elements of hospital organization:
  - Governing body (board of trustees)
  - Medical staff
  - Clinical and administrative staff
    - President of administrative staff serves as liaison between medical staff and hospital administration

## Hospital Organization

- Staff organized by function into departments
  - Each department run by director or chair
  - Organized into multidisciplinary committees
    - Credentialing
    - Quality improvement
    - Utilization review

## Hospital Organization

- Departments or services
  - Diagnosis
  - Therapy
  - Processes
  - Physical environment
  - Support functions

## Hospital Organization

- Matrix management
  - Overlapping areas of departments
  - Ease of decision making
- Product line management
  - End product or category of service

## Hospital Pharmacy Technician

- First in military hospitals or clinics
  - Clerical duties and courier functions
- Roles expanded to:
  - Manufacturing and packaging products
  - Distribution of medications
  - Broad range of clinical, technical, and clerical tasks performed today



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## Hospital Pharmacy Technician

- Roles continuing to evolve
  - More electronically based
  - Unit-dose distribution
  - Purchasing and inventory



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## Structure and Organization of Hospital Pharmacy

- Chief pharmacy officer
  - Part of a larger organization
  - Oversees committees
- Pharmacy director
  - Directs overall operations



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## Structure and Organization of Hospital Pharmacy

- Pharmacist
  - All clinical related functions
- Pharmacy technician
  - Support functions for the pharmacist



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Durgin &amp; Hanan's

# PHARMACY PRACTICE FOR TECHNICIANS

Fifth Edition

## Chapter 3

### Home Health Care

Zachary I. Hanan  
Jane M. Durgin

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## Introduction

- Home health care is defined as provision of health care services to patients in their place of residence.



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## Home Health Care

- First established in 1880s
  - Pharmaceutical services not yet included
- Enactment of Medicare in 1965 increased number of agencies
- Medicare made services available to:
  - Elderly
  - Disabled younger Americans

## Home Health Care

- Pharmacy's role in health care progressed very little until 1983, when Medicare initiated reimbursement.
- Previously, medications not a covered benefit
  - Dramatic shift from in-patient to home care
- Home infusion therapy began in 1970s.

## Home Health Care

- Technological advances, such as IVs, total parenteral feeding (TPN), and central venous catheters made home care more feasible.
  - Medicare willing to pay for TPN
    - Cheaper than in-patient service
  - Many pharmacies opened and provided these infusion services to home care patients.

## Home Health Care

- U.S. costs are a higher percentage of the economy than anywhere else in the world.
- Employers, government, and insurance providers seek ways to manage costs more effectively.
- Number of patients grows as population ages.

## Home Health Care

- Competition among pharmacies will grow.
  - Home care providers may contract with managed care networks.
- Home care will become predominant setting for provision of drug therapies and pharmacy practice.

## Home Health Care Services and Providers

- Encompasses wide range of services, including:
  - Nursing
  - Dietitians
  - Social work
  - Physical and occupational therapy
  - Dental

## Home Health Care Services and Providers

- Home health agencies
  - Public (government)
  - Nonprofit
  - Proprietary
  - Hospital based

## Personal Care and Support Services

- Nonprofessional services to patients in their place of residence
  - Homemaking, food prep, and personal care
  - Performed by home health aides
    - Also called homemakers or personal care attendants
- Second most common

## Personal Care and Support Services

- Private Duty
  - Growing area
  - Services may be provided anywhere from 8 to 18 hours per day or sometimes around the clock.
  - Services may sometimes be provided by a live-in attendant.
  - Services are often not reimbursed by Medicare, Medicaid, or private insurance.

## HME Management Services

- Home medical equipment (HME)
  - Select, deliver, set up, and maintain
  - Educate on use at patient's residence
- HME providers not required to be licensed in most states

## HME Management Services

- Many pharmacies participate
- When respiratory services needed, pharmacies must be involved to either:
  - Provide services
  - Contract with HME provider

## Home Pharmacy Services

- No clear definition since overlap with retail and community pharmacy practice
- Homebound or home care patient
- Medications delivered or shipped to patient's residence
- Pharmacy responsible for monitoring patient's medication on ongoing basis

## Role of Pharmacy in Home Health Care

- Home infusion therapy
  - Medical therapy in patient's residence involving prolonged injection of pharmaceutical products
- Infusion therapy is 90 percent of home pharmacy service.



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## Home Infusion Therapy

- Services provided
  - Pharmacy
  - Nursing
  - Equipment



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## Pharmacy Services

- Compounding and dispensing IV solutions into ready-to-administer forms
- Preparation less frequent
  - For example, one month from preparation to administration
- Script labels must conform to state pharmacy laws.



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## Pharmacy Services

- Pharmacist responsible for pharmaceutical care and clinical monitoring
- Pharmacy technician responsible for most data collection



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## Pharmacy Services

- Home infusion pharmacies
  - Provide nursing supplies, catheter supplies, and access devices
  - Must comply with U.S. Pharmacopeia (USP)



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## Home Nursing Services

- Most home fusion therapy patients initially receive nursing services.
- Overall goal is to teach patient and/or family to administer medications



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## Home Nursing Services

- Primary responsibilities of the home care nurse
  - Educating patient and family
  - Administration of infusion
  - Dressing and site changes
  - Physical assessments
  - Monitoring patient's health



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## Equipment Management Services

- Services provided
  - Select, deliver, and set up infusion control devices
  - Clean and disinfect equipment
  - Maintain equipment
- Equipment must comply with Safe Medical Devices Act of 1990 (SMDA 1990).



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## Equipment Management Services

- Administration methods
  - Pump
  - Gravity
  - Disposable devices
  - IV push directly into vein
- Pharmacy staff responsible for deciding which method



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## Types of Home Infusion Providers

- |  |  |
|--|--|
| – Home pharmacy providers                    | – Hospital pharmacies                  |
| – Physician-based practices                  | – Home health agencies                 |
| – Retail or community pharmacies             | – HME-based providers                  |
| – Institutional or long-term care facilities | – Infusion therapy specialty providers |
|  | – Ambulatory infusion centers          |



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## Physician-Based Practices

- Most common practice model
  - Oncology and infectious disease practices
  - Usually an ambulatory infusion center or physician office
  - Nurses usually prepare the medications



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## Retail or Community Pharmacies

- Provide a variety of services
  - Infusion services are a low component of this type of provider
  - Pharmacists and pharmacy technicians prepare the medications
  - Usually owner operated



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## Institutional or LTC Pharmacies

- Drug distribution services
- Primarily oral medications but do provide some infusion services
- Home infusion is a low percentage of the overall business



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## Hospital Pharmacies

- Home infusion provided by department of pharmacy or outpatient services
- Usually provide equipment and delivery services
- May be a separate satellite office



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## Home Health Agencies

- Pharmacy supplements home health services
- Pharmacy may serve multiple branches of the agency



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## HME-Based Provider

- Supplies respiratory therapy medications that are needed for the home medical equipment and clinical respiratory needs of their patients
- Similar to retail in operation



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## Infusion Therapy Specialty Provider

- Home infusion is the sole business.
- Pharmacy plays dominant role.
- Services center around infusion equipment and delivery.



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## Ambulatory Infusion Centers

- Usually associated with a physician office
- Run and managed by nurses
- Licensed as pharmacies
- Pharmacist or pharmacy technician prepares medications.



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## Preparing and Dispensing Medications for Home Care

- Requires specialized knowledge and skills
- Must be familiar with differences in pharmacy law and regulations
- Compounding practices must adhere to USP 797.



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## Preparing and Dispensing Medications for Home Care

- Timing of preparation and dispensing is critical to delivery of stable, sterile product



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## Role of the Technician in Home Infusion

- Vary from state to state, including:
  - Preparer of sterile products
  - Equipment management technician
  - Patient service representative
  - Purchasing agent or manager



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## Role of the Technician in Home Infusion

- Varies from state to state, including:
  - Warehouse supervisor
  - Billing clerk
  - Case manager
  - Driver or delivery coordinator



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# PHARMACY PRACTICE FOR TECHNICIANS

Fifth Edition

## Chapter 8

### Regulatory Standards in Pharmacy Practice

Zachary I. Hanan  
Jane M. Durgin



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## Introduction

- Rules
  - A guideline for particular actions and procedures
- Regulations
  - Process or procedure as outlined by a particular governing body



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## Statutes, Rules, Regulations, and Quasi-Legal Standards

- Statute
  - An enacted law
  - Enactment of a law begins as a bill that progresses through various steps in government.



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## Statutes, Rules, Regulations, and Quasi-Legal Standards

- Quasi-Legal standards
  - *Quasi* means “similar to”
  - Established by quasi-governmental or private organizations, such as professional pharmacy organizations
  - Are recognized by the federal government and many state governments and can form the basis of laws and regulations



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## Federal versus State and Local Laws

- Practice of pharmacy is basically regulated by state law and is generally under the auspices of the state board of pharmacy.
- A federal law or regulation that pertains to your practice; it may take precedence over state or local law.
- When two or more laws exist in an area, generally the best course is to follow the most stringent law or regulation.



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## State Regulation of Pharmacy Practice

- State boards of pharmacy
  - Ensure that the public is well served professionally by pharmacists, that the drugs distributed and dispensed by the pharmacy within each state meet that state's standards for purity and potency, and that dispensed medications are properly labeled by the pharmacist for the patient's use.



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## Food and Drug Administration (FDA)

- Responsible for assuring that the products under its jurisdiction are safe and effective for their intended use



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## Laws the FDA Enforces

- Pure Food and Drug Act of 1906
  - Prohibited adulteration and misbranding of foods and drugs in interstate commerce
- Federal FDCA of 1938
  - Required new drugs to be proven safe before marketing



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## Federal Regulating Laws

- Kefauver-Harris Amendment
  - Required new drugs to be proven both safe and effective before marketing

## Federal Regulating Laws

- Family Smoking Prevention and Tobacco Control Act
  - Regulation of pharmaceuticals, medical devices, *in vitro* diagnostic products (IVDs), cosmetics, food products, animal drugs and tobacco products that are distributed commercially in the United States and its territories via interstate commerce

## FDA Regulatory Oversight

- Regulates the labeling, marketing, and manufacturing of these products
  - Quality system regulations
- Pharmacy compounded drugs
- New drug development
- Institutional review boards

## FDA Regulatory Oversight

- FDA advisory panel
- Promotion and marketing
- Patents and generic drugs
- Medical devices
- Humanitarian use devices
- Risk evaluation and mitigation strategy

## Centers for Medicare and Medicaid Services (CMS)

- Statutes related to CMS activities
- Federal Anti-Kickback Statute

## Relevant Laws Regarding Pharmacy

- Durham-Humphrey Amendment
  - Established two classes of drugs
    - Prescription
      - No requirement for labels to provide "adequate directions for use"
      - Pharmacist uses directions from prescriber
    - OTC
      - Labels required

## Relevant Laws Regarding Pharmacy

- Medical Device Amendment
  - Provides for more extensive regulation regarding the safety and efficacy of medical devices
- Orphan Drug Act
  - Provides various tax and licensing incentives to drug manufacturers to develop and market orphan drugs for the diagnosis, treatment, or prevention of rare diseases or conditions



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## Relevant Laws Regarding Pharmacy

- FDA Modernization Act of 1997 (FDAMA)
  - Streamlined regulatory procedures by encouraging manufacturers to:
    - Research new uses of drugs
    - Conduct pediatric studies of drugs



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## Controlled Substances Act (CSA) of 1970

- Important federal law regulating manufacture, distribution, and sale of drugs with potential for abuse and dependence
- Classifications:
  - Schedule I
    - No current approved medical use in the United States
    - Abuse potential



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## CSA of 1970

- Classifications:
  - Schedule II
    - High abuse and dependency potential
    - Required to be affixed with orange label and caution statement
  - Schedule III
    - Less abuse and dependency potential



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## CSA of 1970

- Classifications:
  - Schedule IV
    - Minimal abuse and dependency potential
  - Schedule V
    - Contain limited quantities of narcotics



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## Maintenance of Controlled Substances

- Some hospitals and health care facilities authorized to purchase, possess, and use controlled substances
- Must keep many records, including:
  - Order from person authorized to prescribe
  - Separate record at main point of supply for controlled substance



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## Maintenance of Controlled Substances

- Must keep many records, including:
  - Record of authorized requisitions for such drugs
  - Documentation of each substock (amount on nursing unit)
  - Entry on patient's medical administration record (MAR) upon each administration



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## Ordering Controlled Substances

- CSA requirements:
  - Triplicate order forms when ordering substances in Schedules I and II
  - Federal registration of all people in chain of purchase to distribute/dispense



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## Ordering Controlled Substances

- CSA requirements:
  - Anyone who manufactures, distributes, gives instructions about, imports, exports, or administers must register with Drug Enforcement Administration (DEA)



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## Lost/Stolen Controlled Substances or Order Forms

- Federal and state laws have requirements for drug security
- Must be immediately reported to:
  - DEA diversion field office
  - Local police



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## Inventory Requirements

- CSA requires each registrant to make complete and accurate record of all stock on hand.
  - Every two years



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## Destruction of Controlled Substances

- Pharmacy must contact the bureau of controlled substances and/or the DEA to dispose of excess.
- Necessary forms provided to pharmacy



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## Issuing Prescriptions

- Only issued by authorized, licensed individual
  - Licensed in practicing state
- Employee (nurse or secretary) can communicate prescription issued from practitioner to pharmacist
- Only pharmacist can fill prescription



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## Dispensing Controlled Substances

- Only if state law allows, pharmacy technician can dispense under supervision of pharmacist
- Prescriptions must have name of prescriber and signature of physician



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## Dispensing Controlled Substances

- Pharmacist may dispense on oral authorization, but must follow series of steps in accordance with law.



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## Record-keeping Requirements

- All records must be kept for at least two years at place of registration.
- State law may require longer.
  - For example, New York requires 5 years
  - Must adhere to higher standard



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## Federal Hazardous Substances Act

- Requires that certain hazardous household products (“hazardous substances”) bear cautionary labeling to alert consumers to the potential hazards that those products present and to inform them of the measures they need to protect themselves from those hazards
- Consumer Product Safety Commission



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## Poison Prevention Packaging Act

- An amendment to the Federal Hazardous Substances Act
- Regulates certain substances defined as “household substances”
- Requires packaging for consumer use that will make it significantly difficult for children under the age of 5 to open, but not difficult for adults to open within a reasonable time



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## Occupational and Safety Act (OSHA)

- OSHA established
- Created to decrease hazards in the workplace, to maintain a reporting system for monitoring job-related injuries and illnesses, and to develop mandatory job safety and health standards



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## Occupational and Safety Act

- Established Hazard Communication Standard (HCS)
  - Written hazard communication plan
  - Protection from air contaminants
  - Appropriate storage flammable and combustible materials
  - Provision of portable fire extinguishers



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## Omnibus Budget Reconciliation Act (OBRA) of 1990

- Three mandated provisions that affect pharmacy:
  - Drug manufacturers required to provide lowest prices to Medicaid patients
  - Drug use review
  - Patient counseling



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## Omnibus Budget Reconciliation Act (OBRA) of 1990

- Virtually every state has implemented regulations for *all* patients similar to those in OBRA
- Ensures higher level of patient care and professional service



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## Health Insurance Portability and Accountability Act (HIPAA)

- Aimed at improving efficiency and effectiveness of American health care system by adopting national standards for electronic health care transactions
- Requires protection of personal health care information



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## Health Insurance Portability and Accountability Act (HIPAA)

- Title I
  - Insurance reform protects health insurance coverage for workers and their families when they lose their job
- Title II
  - Simplify administrative functions by standardizing health care transactions



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## Regulatory Standards for Marketed Drugs

- Patient package inserts
  - Necessary labeling of medication important for both professional and patient information
  - Required for safe and appropriate prescription use of medication
  - Educate patient on medication



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## Regulatory Standards for Marketed Drugs

- Labeling
  - Prescription drugs labeled for health care professional rather than patient
  - Unit dose packaging used when single dosage of drug is packed for administration
  - Regulated by FDA



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## Regulatory Standards for Marketed Drugs

- National drug code (NDC)
  - Required on all OTC and prescription drugs
  - Ten numbers
    - First five digits identify manufacturer
    - Last five digits identify drug name, package size, and type of drug
  - FDA mandates pharmaceutical bar coding to help reduce medication errors.



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## Regulatory Standards for Marketed Drugs

- Bar codes
  - Mandated by the FDA to help reduce medication errors in hospitals
  - A combination of bars and spaces with varying widths that allow encoding of pertinent information concerning a drug product



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## Orange Book

- Resource for pharmacists to research drug equivalents to generic forms of the drugs
- A two-letter coding system for drug products with therapeutic equivalence is used.



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## Handling of Investigational Drugs

- Main related activities include:
  - Receipt
  - Storage
  - Dispensing
  - Record keeping
  - Control of investigational drugs



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## Reporting of Adverse Drug Reactions

- Hospital policy
  - Brought to the attention of the physician
  - Investigated
  - Documented in the patient's chart
  - Reported to the FDA based on severity
  - Additional state-required reporting



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## Mandatory Device Reporting

- Hospitals or facilities
  - Are legally required to report suspected medical device-related deaths to both FDA and the manufacturer and serious injuries to the manufacturer or if the manufacturer is unknown, to FDA



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## Drug Quality Reporting System

- A voluntary program through which health care practitioners can report drug quality problems
- Maintained by the FDA
- MedWatch



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## Drug Recalls

- All are voluntary.
- Classified as Class I, Class II, and Class III
- Pharmacist or pharmacy technician immediately retrieves all lot numbers of recalled meds and destroys or returns them.



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## Repackaging of Drugs

- Requires a repackaging record
  - Name
  - Strength
  - Lot number
  - Quantity
  - Name of the manufacturer and distributor
  - Date of repacking
  - Number of packages prepared
  - Number of dosage units in each package, the signature of the person performing the repackaging operation, the signature of the pharmacist supervising the repackaging, and other identifying marks added by the pharmacy for internal record-keeping purposes



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## Repackaging of Drugs

- Requires a repackaging record
  - Number of dosage units in each package
  - Signature of the person performing the repackaging operation
  - Signature of the pharmacist supervising the repackaging
  - Other identifying marks added by the pharmacy for internal record-keeping purposes



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## Product Tampering

- Regulations are in place that require OTC, prescription drugs, and medical devices be placed in tamper-proof packaging.
- If the packaging is damaged, it indicates the product was tampered with.



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## The U.S. Pharmacopeia and National Formulary

- Official compendium of drugs in use
- Includes monographs of the drugs
- Provides guidelines for compounding sterile preparations



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## Medicare

- Provides federal health insurance for those older than 65 years of age and for certain disabled individuals, regardless of age
  - Part A – hospitalization
  - Part B – diagnostic services
  - Part D – prescription drugs



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## Long-Term Care Facility Regulation

- Received federal funding
- Need to comply with CMS regulations
- Surveyed annually for compliance



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## Tax-Free Alcohol

- Tax-free ethyl alcohol will be used only for specific purposes:
  - It will not be used for beverage purposes.
  - It is not for resale.
  - It is used in accordance with uses stated on the alcohol permit.
- Regulated by the ATF



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## The Joint Commission

- Formed in 1951
- Mission is to address quality of patient care and safety
- Establishes optimal standards for health care providers



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## The Joint Commission

- Evaluates organizations for compliance with standards through unannounced survey
- Accredits organizations

## The Patient's Bill of Rights

- Ensures that all patients—inpatients, outpatients, and emergency service patients—are afforded their rights